Accordingly, applicants have revised Claims 8 and 11 to further bring out the embodiment of applicants' invention in which the proteinaceous protecting colloid is zein, which is addressed on page 23, indicated line 31, of the application. No new matter has been added.

The Examiner rejected Claims 1 to 6, 8 to 16, 28 to 33, 41 and 42 under 35 U.S.C. §103(a) as being unpatentable in light of the teaching of ***Horn et al.*** **(US 4,522,743)**. In this context, the Examiner acknowledged that ***Horn et al.*** failed to explicitly teach the combined flocculating of the active ingredient and the protective colloid. The Examiner took, however, the position that applicants had not demonstrated unexpected results which accrue from the combined flocculating of the active ingredient and the protective colloid as required in accordance with applicants' invention, and that applicants' invention was, therefore, obvious within the meaning of Section 103(a).

It is respectfully submitted that the legal concept of prima facie obviousness is a procedural tool of examination which allocates who has the burden of going forward with the production of evidence in each step of the examination process.[2)] The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the examiner does not produce a prima facie case, then the applicant is under no obligation to submit evidence of non-obviousness.[3)] It is further respectfully urged that the Examiner has not met the burden to produce a prima facie case that the subject matter of applicants' claims was obvious within the meaning of Section 103(a) in light of the teaching of ***Horn et al.***

Horn et al. teach that it is possible to increase the active ingredient concentration in the dispersion, inter alia, when a mixture of gelatin and gum arabic is employed as the colloid, by forming a sedimentable coacervate of the gelatin and the gum arabic through a pH control.[4)] In this context, ***Horn et al.*** specifically point out that the finely divided carotenoids remain in the liquid phase when the sedimentable coacervate of the gelatin and the gum arabic is formed.[5)] As such, the formation of the coacervate in accordance with the

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2) Cf., for example, In re Rinehart, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976); In re Linter, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972); In re Saunders, 444 F.2d 599, 170 USPQ 213 (CCPA 1971); In re Warner, 379 F.2d 1011, 154 USPQ 173 (CCPA 1967), *cert. denied*, 389 U.S. 1057 (1968).

3) Cf. MPEP §2142, page 2100-128, Rev. 2, May 2004.

4) Cf. col. 3, indicated line 65, to col. 4, indicated line 10, as well as Example 2, col. 6, indicated lines 40 to 56, of ***US 4,522,743***.

5) Cf. in particular col. 4, indicated lines 4 to 10, of ***US 4,522,743***.

teaching of ***Horn et al.*** serves to reduce the amount of colloid which is present in the liquid phase while, at the same time, maintaining the active ingredient in the liquid phase.

In contrast thereto, applicants' invention requires that the proteinaceous protecting colloid be flocculated out of the dispersion together with the active compound. Accordingly, the principle underlying applicants' invention is completely different from the principle upon which the measures taken by ***Horn et al.*** are based. It is well settled that the teaching of a prior art reference is not sufficient to render a claimed invention prima facie obvious within the meaning of Section 103(a) where the modification of the prior art reference which is necessary to arrive at the claimed invention would change the principle of operation of the prior art invention which is being modified.[6] Also, the mere fact that the prior art reference can be modified in some manner so as to arrive at a claimed invention does not support a conclusion of obviousness where the reference fails to suggest the desirability of the specific modification which is required.[7] The teaching of ***Horn et al.*** contains nothing which would have motivated a person of ordinary skill in the art, at the time applicants made their invention, to change the principle of operation of the procedure which is employed by ***Horn et al.*** to obtain the carotenoid or retinoid compositions, nor is there anything within the teaching of ***Horn et al.*** which would have reasonably conveyed to a person of ordinary skill in the art that it was desirable to change the procedure of ***Horn et al.*** such that the colloid is flocculated out of the dispersion together with the active compound as required in accordance with applicants' invention. In light of the standards developed by the courts regarding obviousness under Section 103(a), the teaching of ***Horn et al.*** can therefore not be considered to support the Examiner's position that applicants' invention is rendered prima facie obvious within the meaning of Section 103(a). It is therefore respectfully requested that the rejection of Claims 1 to 6, 8 to 16, 28 to 33, 41 and 42 under Section 103(a) based on the teaching of ***Horn et al.*** be withdrawn. Favorable action is solicited.

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6) Cf. In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

7) Cf., for example, In re Gordon, 733 F.2d 900, 221 USPQ 1125 (CAFC 1984); Interconnect. Planning Corp. v. Feil, 774 F.2d 1132, 227 USPQ 543 (CAFC 1985).

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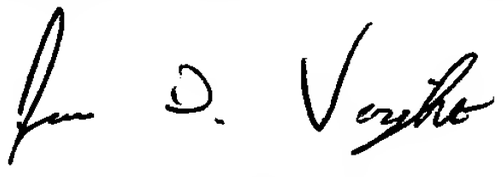
Respectfully submitted,

NOVAK DRUCE DELUCA & QUIGG, LLP



Jason D. Voight
Reg. No. 42,205

1300 Eye Street, N.W.
Suite 400 East Tower
Washington, D.C. 20005
(202) 659-0100

Encl.: CLAIM AMENDMENTS (Appendix I)

JDV/BAS

APPENDIX I:

CLAIM AMENDMENTS:

Amend Claims 8 and 11 as indicated in the following listing of the claims:

1. (*previously presented*) A process for producing solid preparations of at least one water-soluble, sparingly water-soluble or water-insoluble active compound suitable for the food and animal feed sectors or for pharmaceutical and cosmetic applications by

   a) dissolving or dispersing at least one of the abovementioned active compounds in an aqueous molecular dispersion or colloidal dispersion of a proteinaceous protecting colloid,

   b) flocculating the proteinaceous protecting colloid together with the active compound out of the dispersion by setting the pH of the dispersion to a value which is in the range of the isoelectric point of the protein used as protecting colloid,

   and

   c) separating off the flocculated solid from the water and any solvents additionally used and subsequently converting them into a dry powder.

2. (*original*) A process as claimed in claim 1 for producing solid preparations of at least one sparingly water-soluble or water-insoluble active compound suitable for the food and animal feed sectors or for pharmaceutical and cosmetic applications, wherein, in process step a), at least one of the abovementioned active compounds is dispersed in an aqueous molecular dispersion or colloidal dispersion of a proteinaceous protecting colloid.

3. (*original*) A process as claimed in claim 2, wherein the dispersion step a) is the production of a suspension of at least one solid active compound in an aqueous molecular dispersion or colloidal dispersion of a proteinaceous protecting colloid.

4. (*original*) A process as claimed in claim 3, wherein the suspension produced in process step a) is ground before the flocculating.

5. (*original*) A process as claimed in claim 2, wherein the dispersion in stage a) comprises the following steps:

a_1) dissolving one or more sparingly water-soluble or water-insoluble active compounds in a water-miscible organic solvent or a mixture of water and a water-miscible organic solvent or

a_2) dissolving one or more sparingly water-soluble or water-insoluble active compounds in a water-immiscible organic solvent and

a_3) mixing the solution obtained by a_1) or a_2) with an aqueous molecular dispersion or colloidal dispersion of a proteinaceous protecting colloid, the hydrophobic phase of the active compound being produced as nanodisperse phase.

6. (*original*) A process as claimed in claim 5, wherein, when process step a_2) is being performed, the water-immiscible solvent is distilled off before flocculating the protecting colloid.

7. (*canceled*)

8. (*currently amended*) A process as claimed in claim 1, wherein the protecting colloid is <u>zein,</u> casein or a caseinate.

9. (*original*) A process as claimed in claim 1, which involves the production of carotenoid-containing dry powders.

10. (*original*) A process as claimed in claim 9 for producing dry powders comprising carotenoids selected from the group consisting of astaxanthin, β-carotene, β-apo-8'-carotenal, β-apo-8'-carotenic acid ethyl ester, canthaxanthin, citranaxanthin, echinenone, lutein, lycopene and zeaxanthin.

11. (*currently amended*) A process as claimed in claim 9, wherein

a) one or more carotenoids are dissolved in a water-miscible organic solvent, or a mixture of water and a water-miscible organic solvent, at temperatures above 30°C,

b) the resultant solution is mixed with an aqueous <u>solution of zein,</u> casein ~~solution~~ or caseinate ~~solution~~,

c) the <u>zein,</u> casein or caseinate is flocculated out of the dispersion together with the carotenoid at a pH of the dispersion which is in the region of the isoelectric point of <u>zein,</u> casein or caseinate,

d) the flocculated solid is separated off from the water and solvent and dried.

12. (*original*) A solid preparation of at least one water-soluble, sparingly water-soluble or water-insoluble active compound suitable for the food and animal feed sectors or for pharmaceutical and cosmetic applications and obtainable by a process as defined in claim 1.

13. (*original*) A solid preparation as claimed in claim 12 comprising at least one sparingly water-soluble or water-insoluble active compound suitable for the food and animal feed sectors or for pharmaceutical and cosmetic applications.

14. (*original*) A solid preparation as claimed in claim 12 having an active compound content of from 0.1 to 80% by weight.

15. (*original*) A solid preparation as claimed in claim 13 which is a carotenoid-containing dry powder.

16. (*original*) A dry powder as claimed in claim 15 comprising carotenoids selected from the group consisting of astaxanthin, β-carotene, β-apo-8'-carotenal, β-apo-8'-carotenic acid ethyl ester, canthaxanthin, citranaxanthin, echinenone, lutein, lycopene and zeaxanthin.

17. - 27. (*canceled*)

28. (*previously presented*) An oily suspension comprising, as disperse phase, solid preparations of at least one water-soluble, sparingly water-soluble or water-insoluble active compound suitable for the food and animal feed sectors or for pharmaceutical and cosmetic applications which are obtainable by

a) dissolving or dispersing at least one of the abovementioned active compounds in an aqueous molecular dispersion or colloidal dispersion of a proteinaceous protecting colloid,

b) flocculating the proteinaceous protecting colloid together with the active compound out of the dispersion by setting the pH of the dispersion to a value which is in the range of the isoelectric point of the protein used as protecting colloid,

and

c) separating off the flocculated solid from the water and any solvents additionally used and subsequently converting them into a dry powder.

29. (*original*) An oily suspension as claimed in claim 28 having an active compound content of from 0.1 to 50% by weight, based on the total amount of oily suspension.

30. (*original*) An oily suspension as claimed in claim 28 comprising as active compound at least one carotenoid selected from the group consisting of astaxanthin, β-carotene, β-apo-8'-carotenal, β-apo-8'-carotenic acid ethyl ester, canthaxanthin, citranaxanthin, echinenone, lutein, lycopene and zeaxanthin.

31. (*previously presented*) A process for producing a carotenoid-containing oily suspension comprising, as disperse phase, at least one carotenoid selected from the group consisting of astaxanthin, β-carotene, β-apo-8'-carotenal, β-apo-8'-carotenic acid ethyl ester, canthaxanthin, citranaxanthin, echinenone, lutein, lycopene and zeaxanthin, which carotinoid is enclosed by one or more protecting colloids, with the proviso that the oily suspension comprises no water-soluble vitamins, which process comprises

a) grinding a dry powder comprising the at least one carotenoid enclosed by one or more protecting colloids in at least one oil to a mean particle size of from 0.1 to 100 μm or

b) grinding a dry powder comprising the at least one carotenoid enclosed by one or more protecting colloids without using a continuous phase to a mean particle size of from 0.1 to 100 μm and then suspending the ground particles in at least one oil or

c) grinding a carotenoid-containing suspension comprising, as solid phase, the at least one carotenoid enclosed by one or more protecting colloids and, as dispersion medium, water or a mixture of water and a water-miscible solvent to a mean particle size of from 0.1 to 100 μm, then freeing the solid phase from the water or water/solvent mixture and suspending the resultant ground particles in at least one oil.

32. (*original*) A process as claimed in claim 31, wherein the oil is an edible oil liquid at 20°C.

33. (*original*) A process as claimed in claim 31, wherein the oil is a hard fat solid at 20°C.

34. - 40. (*canceled*)

41. (*previously presented*) The process of claim 1, wherein the proteinaceous protecting colloid and the active compound are flocculated by setting the pH value in stage (b) in a range of from one pH unit above the isoelectric point of the protein to one pH unit below the isoelectric point of the protein.

42. (*previously presented*) The suspension defined in claim 28, which is obtained by a process in which the proteinaceous protecting colloid and the active compound are flocculated by setting the pH value in stage (b) in a range of from one pH unit above the isoelectric point of the protein to one pH unit below the isoelectric point of the protein.